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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/20/2008

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EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

08/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/942,137	<b>Applicant(s)</b> ANGELUCCI ET AL.	
	<b>Examiner</b> Pedro Philogene	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 16-21 and 69-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13-14, 16-21, 69-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,5, 6,16-21,69 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay (5,702,449) in view of Zucherman et al. (5,836,948).

McKay discloses an implant for use in a patient's spinal column in connection with a laminoplasty procedure of a cut bone having first and second segments; as best seen in FIG.3, the implant comprising: a body (15) portion having a length, a width, a depth, and a longitudinal axis, the body portion being configured to be insertable between the first and second bone segments (v), the body portion having an outer surface forming a hollow region (18), the hollow region having a longitudinal axis coaxial with the longitudinal axis of the body portion, the hollow region comprising most of the volume of the body portion, the body portion further having first and second open ends; as best seen in Fig.2, for contacting the first and second bone segments, the body portion having an inner side region and an outer side region; as best seen in FIG.3;

Although McKay discloses a plurality of connecting means for attaching the body to the bone segments (V), It is noted McKay did not teach of at least one of the first and second open ends comprises a single bone receiving channel extending there across that has a first depth measured from the crotch of the channel to the outer surface of the inner side region at the at least one end, the first side extending along the length of the

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body portion, the channel also having a second depth measured from the crotch of the channel to the outer surface of the outer side region at the at least one end, the second side extending along the length of the body portion, the second side opposite the first side, the first depth being less than second depths, and a centerline of the side opposite the first side, the first and second side depths having different measurements; as claimed by applicant. However, in similar art, Zucherman et al; as set forth in column 15, lines 55-67, column 16, lines 1-67, column 17, lines 1-9; and as best seen in FIGS.63-66, 74-78, provide the evidences of the use of such a single bone receiving channel, as above and as claimed by applicant; such that the implant can be easily and conveniently inserted, will not migrate forwardly and will hold its position through flexion and extension as well as lateral bending of the spinal column.

Therefore, given the teaching of Zucherman et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the attaching means of McKay, as taught by Zucherman et al such that the implant can be easily and conveniently inserted, will not migrate forwardly and will hold its position through flexion and extension as well as lateral bending of the spinal column.

Claims 3-4,7,8,13,14, 15, 70,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay (5,702,449) in view of Zucherman et al. (5,836,948) In view of Sander et al. (7,048,762).

It is noted that the above combination of references did not teach of an implant made of bone allograft material wherein a portion of the first and second ends comprises demineralized cortical bone wherein the bone is obtained from a cross-

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section of a donor bone having an intramedullary canal, and wherein the inner surface of the implant is defined by the intramedullary canal of the donor bone and the volume of the hollow region is greater than the intramedullary canal of the donor bone.

However, in a similar art, Sander et al evidence the use of an elongated cortical bone implant taking from the long bone to increase the size of the canal to receive more bone material and to match, as much as possible, the natural external curvature of the lumbar vertebrae.

Therefore, given the teaching of Sander et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of McKay/Zucherman et al, as taught by Sander et al., to increase the size of the canal to receive more bone material and to match, as much as possible, the natural external curvature of the lumbar vertebrae.

### ***Response to Amendment***

Applicant's arguments, see Remarks, filed 4/14/08, with respect to the rejection(s) of claim(s) 1-8,13-21,23-25,53-58,60,62-66,69-71 under 102/103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of McKay. See rejection above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/  
Primary Examiner, Art Unit 3733  
August 16, 2008